This concentrated extract solution was then analyzed by LC-MS using the Waters Q-TOF instrument with the electrospray source in positive ion mode and observed at least one of the peaks of interest in the mass spec TIC chromatogram; the mass spectrum of the peak has been obtained and appears to have what might be the molecular ion peak at m/z 158; exact mass analysis of this peak and its pattern of isotope peaks predicts some empirical formulas. Compounds with these empirical formula and known usage in the rubber industry were tested but without success.

Solvent extracts of the stoppers were prepared and analyzed by gas chromatography-mass spectrometry. Analysis revealed the presence of two low molecular weight rubber oligomers previously reported by Helvoet. These oligomers are not commercially available for identification confirmation; however, their hydrophobic character makes it unlikely that they would elute near dexmedetomidine in the related substances HPLC method.

A pure extractable sample was isolated by combining multiple fractions collected from repeated HPLC separations of a stopper extract. Attempts to obtain an EI+ mass spectrum by direct probe mass spectrometry and gas chromatography-mass spectrometry were unsuccessful, suggesting that the stopper extractable is nonvolatile and possibly thermally labile.

The pure extractable sample was analyzed by IR and elemental analysis. Both of these techniques suggested that the extractable contains only carbon, oxygen and hydrogen. No indication of nitrogen, sulfur or any other heteroatom was observed.

The chemical additives that perform variety of functions, including plasticizers, fillers, etc are the most significant source of chemical entities observed as extractables. There are several reasons which makes identifying the extractables challenging and at times impossible. Each functional additive category contains representatives from several molecular structures. For example, consider the category of anti-degradants, subcategory antioxidants, which includes aromatic amines, sterically hindered phenols, phosphites, phosphonites, and thioethers. To further complicate the picture, chemical additives are often not pure compounds but mixtures of related structures. For examples "Abietic Acid" which is an organic chemical filler used in certain types of rubber, in reality is a complex mixture of chemical entities, all of which could appear as extractables/leachables. Chemical additives can also react and degrade within the rubber/polymer matrix during or subsequent to compounding process. As an example of this consider, the trivalent phosphorus, or phosphate antioxidant, a common tradename for which is Irgafos 168. This compound reacts with and thereby destroys oxidizing agents, such as hydroperoxides, to form the corresponding pentavalent phosphorus species, or phosphate.

In addition to the foregoing, the following must also be considered when analyzing extractables/leachables:

Monomers and high molecular weight oligomers derived from incomplete polymerization reactions.

Surface residues, such as heavy oils and degreasing agents on the surface of metal canisters and containers.

Chemical additives on the surfaces of container closure component fabrication machinery, such as mould release agents, antistatic and antislip agents, etc.

The present invention is not to be limited in scope by the specific embodiments described herein. Indeed, various modifications of the invention in addition to those described herein will become apparent to those skilled in the art from the foregoing description. Such modifications are intended to fall within the scope of the appended claims.

Patents, patent applications, publications, product descriptions, and protocols are cited throughout this application, the disclosures of which are incorporated herein by reference in their entireties for all purposes.

What is claimed is:

1. A ready to use liquid pharmaceutical composition for parenteral administration to a subject, comprising dexmedetomidine or a pharmaceutically acceptable salt thereof disposed within a sealed glass container, wherein the liquid pharmaceutical composition when stored in the glass container for at least five months exhibits no more than about 2% decrease in the concentration of dexmedetomidine.

2. The ready to use liquid pharmaceutical composition of claim **1**, wherein the dexmedetomidine or pharmaceutically acceptable salt thereof is at a concentration of about 0.005 to about 50 ug/mL.

3. The ready to use liquid pharmaceutical composition of claim **1**, wherein the dexmedetomidine or pharmaceutically acceptable salt thereof is at a concentration of about 0.05 to about 15 ug/mL.

4. The ready to use liquid pharmaceutical composition of claim **1**, wherein the dexmedetomidine or pharmaceutically acceptable salt thereof is at a concentration of about 0.5 to about 10 ug/mL.

5. The ready to use liquid pharmaceutical composition of claim **1**, wherein the dexmedetomidine or pharmaceutically acceptable salt thereof is at a concentration of about 1 to about 7 ug/mL.

6. The ready to use liquid pharmaceutical composition of claim **1**, wherein the dexmedetomidine or pharmaceutically acceptable salt thereof is at a concentration of about 4 ug/mL.

7. The ready to use liquid pharmaceutical composition of claim **1**, further comprising sodium chloride at a concentration of between about 0.01 and about 2.0 weight percent.

8. The ready to use liquid pharmaceutical composition of claim **7**, wherein the sodium chloride is present at a concentration of about 0.9 weight percent.

9. The ready to use liquid pharmaceutical composition of claim **1**, wherein the composition is formulated as a total volume selected from the group consisting of 20 mL, 50 mL and 100 mL.

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